

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 52-55, 79-85, 87, and 101-127 are in this Application. All previously pending claims have been rejected under 35 U.S.C. § 112. Claim 113 is rejected under 35 USC 101. Claims 52-55, 79-85, 87 and 101-112, 114, 115 and 120-123 have been rejected under 35 U.S.C. § 102. Claims 53, 54, 83, 84, 113 and 116-119 have been rejected under 35 U.S.C. § 103. Claims 52, 53, 79, 104, 107, 109, 111, 113, 116, 122 and 123 are amended herewith. New claims 124-127 are added herewith.

Priority

The Examiner has rejected the priority claim based on a lack of support for the various claim limitations in combination. Applicants have amended claim 52 and also argue against the Examiner's position. Applicants are responding herein by providing citations by document and page number, as requested.

Claim 52 as currently amended has two limitations which the Examiner suggests are "mixed embodiments", namely, (a) that there is an electrode configured to be mounted attached to muscle in the abdominal cavity and (b) that a pulse is between 1 millisecond and 2 seconds in length (amended limitation, but issue similar). An additional limitation added is (c) the use of timing circuitry.

Applicants refer to US patent 7,006,871, which corresponds to the priority document. In this patent, it is clear that the system of Fig. 1 can have various types of electrodes, as described in the section "types of electrodes" at Col. 19, line 23 and especially at col. 20, lines 57-62. Furthermore, the single experiment described at column 25 line 5 relates specifically to using an electrode attached to abdominal muscles. At the same time, it is made clear that the same system of Fig. 1, can have various pulse shapes and parameters, as indicated in a section by that name, at Col. 15, line 18. It is clear from the structure of the application and from the explicit language in each of these sections and from the explicit language at the top of Col. 26, that it is intended that the scope of the claims include such combinations as the applicants have made. With regard to the new limitations regarding pacing and lack of excitation of tissue, the Examiner is directed to the first paragraph of the detailed description, at col. 8, lines 23-24, where the combination of pacing and non-excitatory

signals is explicitly described in the context of Fig. 1. Col. 23, lines 13-20 further relate to properties which are optionally applied to all embodiments, namely avoidance of undesirable excitation. Attention is also directed to the option described at col. 23, lines 3-5 of the electrodes to be wholly enclosed by the intestines, which illustrates the range of options conceived of.

In summary, applicant feels that the instant claim 52 is not only supported in parts, but that its combination of limitations is also clearly supported in the priority document.

35 U.S.C. § 112 Rejections

Claim 52 and all claims dependent thereon are rejected as failing to comply with the written description requirement. The Examiner argues that the specification does not include support for (a) the combination of using a needle electrode with the stomach or intestine stimulation; (b) the open ended length of pulse; and (c) length of pulse train. Applicants traverse in part and amend in part.

Applicants have amended the claim so the train length limitation is deleted and the pulse length is rewritten to be between 1 millisecond and 2 seconds, which applicants believe the Examiner will agree is supported.

With regard to the combination of needle electrode and stomach stimulation, applicant is confused. Claim 52 is not limited to stomach and/or intestine stimulation. Furthermore, as argued above, the application, as filed (even in the priority document) clearly teaches that the configuration of electrodes can be used with any of the taught stimulation sequences. Furthermore, pages 55-56 of the instant application relate to the link between stomach and pancreatic stimulation.

Claim 53 is rejected as the Examiner was unable to find support for components which relate to “desired” and “certainty”.

Applicants thank the Examiner for a detailed explanation of what is problematic about the claim. Applicants have amended claim 53 so that it is rewritten in terms of concrete elements, thereby presenting the “overstimulation in case of doubt” with reference to concrete features described, for example, in the section entitled “calibration and programming” on pages 58-61. It is hoped that the instant claim amendment overcomes the Examiner’s rejection. In addition, applicants note that “certainty” and “desired” are properties of the design of a control loop and need not be properties measured by the final control loop.

Claim 79 is rejected as the Examiner notes that application allows a glucose control including both insulin and non-insulin manners to be combined. Claim 79 is hereby broadened to allow for this.

Regarding claims 106, 107, 110 11, 113-118, 120 and 121 the Examiner objects that the limitations therein seem to relate to embodiments where the electrode is attached to the stomach. However, as noted above, the application is clear that the variations in the location of the electrodes is expected to be combined with the variation in signal properties. That particular experiments describe only some options is to be expected from the limitation on ability to carry out experiments. However, the teaching of the application as a whole and especially pages 55-56 thereof is that the limitations found in one set of embodiments is to be used with another set of embodiments, which are directed at illustrating different particular features.

Regarding claim 115, the Examiner does not find support for “at least 15 minutes”. Applicant point at two locations, first, original claim 22 which teaches applying for 15 minutes or more and, second, in several locations, for example, the Examples of Figs. 32-36, which teach applying a signal for 15 minutes or more during digestion.

Regarding claim 116, the Examiner does not find support for the range of at least 0.5 seconds or the repetition for 5 detections. These are supported by the Experiment of Figs 38A-38D. The limitation of 0.5 is found on page 44 (500 milliseconds). A new dependent claim 127 which reads “1 second” is provided to more closely match this example.

Regarding claim 117, “less than 20 seconds” is supported by page 44, where the pulse being applied is said to be 20 seconds or less.

Regarding claim 118, “less than 10 seconds” is supported by, for example, page 73, lines 13-15 (Figs. 38A-38D).

Regarding claim 119, not affecting nervous tissue is described at page 55, lines 19-23

Regarding claim 120, also pacing the stomach is described, for example, in US 6,571,127 which is incorporated by reference at page 56, at the paragraph bridging columns 16 and 17.

Regarding claim 121, not exciting the stomach and pancreas is described in several places, including the first paragraph of the detailed description and the

discussion on pages 55-57 and the description of the experiments with respect to Figs. 38-39 and also as noted above where avoiding of excitation of tissue is described.

In addition, claim 53 was rejected as lacking enablement. The Examiner states that it is not taught how the apparatus can be certain about the achievement of glucose reduction. As noted above, the claim was amended and this rejection should be moot. Also, Applicants note that the application teaches that in some embodiments the apparatus tracks the effects of its treatment, exactly for the purpose of linking cause and effect. In general, applicants note the following regarding “desired” glucose levels. While there is a range of “acceptable values” for glucose levels, applicants contend that in the art any such level would be approached from above, due to the desire to reduce glucose level as much as possible, while avoiding overshooting and hypoglycemia. In contrast, the design of the apparatus claimed is less concerned with hypoglycemia and can allow overshooting. Applicants respectfully submit that the Examiner has not shown art that teaches overshooting a target glucose level.

Claims 53, 104, 107, 111, 122 and 123 were rejected as being indefinite. Some claims were amended. In general, the amendments are cosmetic and do not change the claim scope.

In claim 53, it was not clear if all the “desired” refer to the same items. It is believed the amendments to claim 53 clarify this issue.

In claim 104 it was not clear what element is being limited. Claim 104 was amended and it is believed this issue is overcome.

In claim 107 it was unclear what “local” means. The claim has now been amended.

In claim 111 “said electrodes” lack an antecedent. The claim has been amended to overcome this issue.

In claim 115, the Examiner states it is unclear if a sensor is required. Applicant respectfully submits that application teaches various embodiments, some with sensor, some with a transmitter. Applicant therefore considers the claim is clear.

In claim 116 the Examiner objected that there is no element to sense an action potential. Considering the amendments to claim 52 and 116, it is believed this issue is mooted.

In claim 122, the digestion sensor is now positively recited as suggested by the Examiner.

In claims 109 and 123, applicants have amended the claims to follow the Examiners suggestions.

35 U.S.C. § 101 Rejection

Claim 113 is rejected as it includes a part of the human body. Applicants have amended claim 113 as per the Examiner's suggestion to avoid this rejection.

Art Rejections, General

In the previous response, applicants tried to put the cited art, Wernicke and Marchal, in context. Wernicke is directed at a method of modulating pancreatic function by nerve stimulation. Such modulation is not shown to be effective for treatment of hyperglycemia and even for such treatment it is admitted that a closed loop using an unavailable sensor, is to be used.

Marchal, while using very general terms of what might be controllable in a pancreas and how this might be achieve, does not actually describe control of anything close to blood glucose levels, nor even suggest that such would be an aim of treatment using his system.

However, this did not seem to convince the Examiner, who argued, basically, that if the device is capable of the function, due to overlap in signal parameters, for example, then there is anticipation. Applicants disagree with the Examiner's rejection, but in order to advance the case to allowance choose to add a specific structural limitation of timing circuitry which takes into account electrical activity. Such electrical activity is neither sensed nor caused and definitely not related to by any parts of the devices of Wernicke or Marchal.

It is noted that while some of the art might arguably (this is not admitted) show or suggest closed loop systems, any such loops relate to the effect of stimulation, rather than to synchronization with electrical activity.

35 U.S.C. § 102 Rejection

Claim 52 and claims dependent thereon are rejected as being anticipated by Wernicke. Applicants respectfully disagree. First, claim 52 has been amended to include sensing tissue activation or providing a pacing signal. Wernicke is related to nerve stimulation. In vagus nerve stimulation in general, and in Wernicke in particular, it is not described to sense the vagus nerve activity or to use a combination of excitatory and non-excitatory signals.

Applicants further disagree with the Examiner's contention that Wernicke implies mounting the electrode on the stomach because the vagus nerve is near the stomach. To the contrary, Wernicke described (Fig. 3) electrodes specifically designed for nerve stimulation and while one can argue regarding attaching the lead of Wernicke to the stomach or other muscle, there is definitely no teaching that the electrode itself would be so attached. Similarly, electrodes designed for nerve stimulation generally encircle the nerve and are not suitable for attachment to muscle.

The specific pulse limitations and feedback loops or dependent claims are also not taught in Wernicke.

Claim 52 and claims dependent thereon are rejected as being anticipated by Marchal. Applicant has amended claim 52 to include limitations regarding circuitry for synchronization to electrical activity. This is not taught or suggested in Marchal. In particular, Marchal does not teach any combination of excitatory and non-excitatory signals.

The dependent claims are patentable at least for reason of being dependent on an allowable independent claim. However, some dependent claims are argued as well.

For example, claim 53, as now amended should be clearly distinguished over Marchal and/or Wernicke who do not describe a system with overshoot and synchronization to electrical activity of tissue.

35 U.S.C. § 103 Rejections

Claims 53, 54, 83, 84, 113 and 116-119 are rejected under 35 USC 103 as being unpatentable over Marchal in view of Wernicke. Applicants respectfully disagree with the reasonableness of the combination. This disagreement has been raised in the previous response to office action and it does not seem that the Examiner related to it. The argument is repeated again, with some modification.

Marchal is directed at pancreatic and other stimulation without the aim of glucose level control. Wernicke is specifically directed at glucose level control. A person of typical skill in the art would not consider protocols or a device suitable for treating one family of conditions for use in another family of conditions, especially as the result of keeping blood glucose level accurately within acceptable limits is not actually taught in either patent and is definitely not predictable from the combination. Such a result is a holy grail of Diabetes management. See for example, Col. 2 of Wernicke, where the need is explained, however, while various protocols are suggested, no results are shown and there is no justification for any expectation that a treatment other than closed loop with stimulation (Col. 4, line 44-Col. 3, line 26) only to the amount indicated by the sensed glucose level would be used to provide actual control of hyperglycemia (cf. Col. 4, lines 16-30).

There is no reason for a person or ordinary skill in the art to consider a vagus nerve stimulator for glucose control when building a pancreatic stimulator which is Not intended for glucose control, or vice versa. Furthermore, it is suggested that the lack of any teaching in Marchal of treating diabetes is a teaching away from any such use, as Marchal was clearly aware of the need to treat diabetes.

New claims

New claims 124 and 125 provide various options for the timing circuitry. New claim 126, based, for example, on the description of Figs. 38A-38D provides a limitation for a train length.

Provisional obviousness-type Double patenting

When claims are allowed and if still necessary, applicant intends to consider the filing of a terminal disclaimer.

In view of the above amendments and remarks it is respectfully submitted that claims 52-55, 79-85, 87 and 101-126 are now in condition for allowance. A prompt notice of allowance is respectfully and earnestly solicited.

Respectfully submitted,

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